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PRINCIPAL INVESTIGATORS: Richard A. Sherman, LTC, MS
Kent M. Karstetter, MAJ, MS
Howard May, LTC, MS

CONTRACTING ORGANIZATION: Fitzsimons Army Medical Center
Department of Clinical Investigation
Aurora, CO 80045-5001

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Richard A. Sherman, LTC, MS
Kent M. Karstetter, MAJ, MS; Howerd May, LTC, MS

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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13. ABSTRACT
This project is (a) developing predictive methodologies for relating heat patterns observed in the lower limbs of trainees just inducted into the Army to pain syndromes developed during training, (b) comparing the effectiveness of three methods of recording heat patterns in the lower limbs in field environments, (c) determining the utility of shock absorbing boot inserts for reducing the occurrence of lower limb pain among trainees, and (d) evaluating the usefulness of videothermography for tracking the resolution of lower limb pain problems.
Recruits arriving at their basic training sites have an unexpectedly high rate of heat asymmetries in their lower limbs. Most of the trainees developing lower limb pain during basic training had asymmetries at the start of training. Those with the most asymmetrical patterns are most likely to experience pain. Contact thermographs have so many problems visualizing common problem areas that they are not useful in the Army field environment. A suitable grid system has been be developed which permits the single point infrared thermometers already in use throughout the Army to be substituted.

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FOREWORD

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Richard L. Johnson 31 Jan 92

Principal Investigator's Signature Date

Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers

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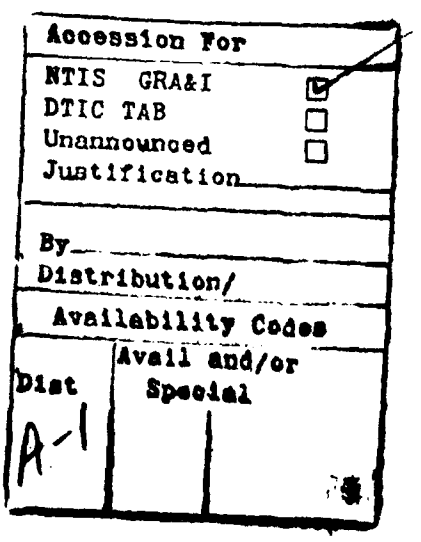


USE OF BODY SURFACE HEAT PATTERNS FOR PREDICTING AND EVALUATING ACUTE LOWER EXTREMITY PAIN AMONG SOLDIERS

1. INTRODUCTION:

a. Aim for entire project: To determine the usefulness of surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers. This study is being performed in two phases. The first phase contained two overlapping projects which are now complete. The first project of phase one used heat patterns to detect abnormal blood flow patterns in the lower limbs of recruits who had not yet begun their training. The aim of this portion of the study was to develop predictors of problems which develop during training. The second project compared the effectiveness of three methods for recording surface heat patterns in order to determine which might be appropriate for use in the field environment. Phase two also contains two overlapping projects. The first is intended to determine whether having trainees begin using shock absorbing inserts in both their sneakers and boots prior to beginning basic training will reduce the occurrence of lower limb pain. The second will determine whether videothermography is a valuable tool to use in fixed medical facilities to screen soldiers with pain and to track the resolution of the pain once treatment has been initiated.

Hypotheses:

(1) That thermography will be an efficient screening tool for predicting which trainees are likely to require treatment for problems in their knees, lower legs, and feet during training. This incorporates the sub-hypothesis that there will be a minimal number of false positive findings in which trainees appear abnormal during initial screening but never require treatment and that there will be a relatively minimal number of false negative findings in which soldiers producing normal thermograms who require treatment for the problems of interest. We predict a relatively high rate of false negatives because many of the solders will injure their knees, lower legs, and feet during training even though they may not have been predisposed to do so.

(2) That thermography will be an effective way to track the resolution of pain in the knees, lower legs, and feet as well as a good predictor of which trainees will experience a reoccurrence of problems in these areas after treatment.

(3) That inserts placed into the boots and sneakers of trainees will significantly reduce the occurrence of lower limb pain and abnormal thermographic patterns.

(4) That inexpensive, portable contact thermographs can produce instant Polaroid pictures from two or three standardized views of the feet or legs which attending health care providers can immediately use to accurately determine the presence or absence of stress fractures.

(5) That beam thermometers can not provide sufficient information about heat patterns in a limb during a reasonably brief session to be of assistance in recognizing the clear patterns produced by stress

fractures because there is no way to predict exactly where on the limb differences should occur.

c. Objectives:

(1) To demonstrate the usefulness of thermography in predicting injuries to the lower limbs during basic training.

(2) To demonstrate the usefulness of thermography for identifying the presence of vascular related lower limb pain problems and tracking the resolution of those problems throughout treatment.

(3) To avail the medical practitioner with a field viable, convenient, non-invasive, quick, and accurate modality for the diagnosis of stress fracture in troops by establishing the efficiency of contact thermography and beam temperature monitoring relative to standard tests.

(4) To determine the ability of shock absorbing boot and sneaker inserts to reduce the occurrence of lower limb pain and abnormal thermograms during basic training.

d. Goals:

(1) For the first phase of the project (all MET - phase over):

(a) Establish the rates of false positives and abnormalities found during baseline recordings among these troops.

(b) Relate abnormalities found during baseline recordings to occurrence of lower limb pain and abnormal thermograms during training.

(c) Establish the usefulness of videothermography and thermometers for determining patterns of heat emanating from the lower limbs.

(2) For the second phase of the project (started last month):

(a) Determine whether having trainees wear shock absorbing inserts in their sneakers and boots throughout basic training reduces the rate of occurrence of lower limb pain and abnormal thermograms.

(b) Determine whether videothermography is effective in fixed facilities for screening lower limb pain and for tracking its resolution.

e. Status:

(1) Lower extremity injury rate during basic training: the US Army Research Institute of Environmental Medicine recently completed a review and study of both the incidence and risk factors for injury among Army basic trainees (Jones et al, 1988, Cowan et al 1989). These exhaustive reviews of the literature were combined with detailed studies of actual injury rates among basic trainees. The excellent prospective studies concluded that 51% of females and 27% of males are injured during basic training. Of 124 men and 186 women studied in detail, the men lost 99 days of full training while the women lost 481 days of full training. However, initial physical fitness was an excellent predictor of injury and when pre-training level of fitness was factored in, the difference between males and females disappeared. The risk of sustaining lower extremity injuries sufficiently severely to significantly interfere with training was 45% for

females and 21% for males. Of these, 11% of females and 2 percent of males sustained stress fractures. In a separate study, 129 sustained injuries to their lower extremities which resulted in significant losses of training time. Nine of these were stress fractures. Illness rates were similar for both sexes (after adjustment for gynecological problems) and only caused a loss of 23 and 19 full training days for women and men respectively. The results of these studies parallel the results of the large demographic and clinical studies reviewed by the authors. These rates of injury become especially noteworthy when it is noted that traumatic events initiating the problems are rare. Volpin et al (1989) recently reviewed 105 lower limb pain cases among recruits and found that 54% had stress fractures when diagnosed using technetium scans. Of the remaining recruits without evidence of stress fractures, 74% had anatomical deformities of the lower limb. Thus, lower extremity injury during basic training is a very significant factor in training effectiveness.

(2) Confirmation of the diagnosis of stress fracture: Stress fractures are very difficult to confirm. The study by Volpin et al (1989) discussed above is typical of the vast majority of studies in which x-rays and other techniques are compared in the evaluation of stress fractures. They found that x-rays gave false negative results in 87% of cases documented using scans. The vast majority of stress fractures occur among soldiers who are far from major medical centers having the powerful (as well as heavy, delicate, expensive, difficult and time consuming to use, and immobile) equipment required to perform accurate bone scans. This is the main reason that methods capable of evaluating stress fractures in the field must be identified. It is important to accurately diagnose stress fractures to minimize the amount of time the soldier is away from the unit and to minimize reoccurrence of immobilizing pain due to incorrect treatment. Problems with the use of x-rays for evaluation of stress fractures and the effects of delaying treatment were reviewed by Devereaux et al (1984).

(3) Use of patterns of heat emanating from the body's surface as an aid to medical diagnosis: The use of heat emanating from the body's surface to detect disease processes is of ancient origin. The recent application of modern videothermographic methodology to detect near surface blood flow patterns is simply a refinement of the older techniques of feeling the body's surface. Videothermographs look very much like television cameras and work in a parallel way. The basic difference is that heat emanating from the body's surface is recorded rather than light reflecting off of it as is done with traditional light television. Thus, the system is safe and non-invasive as nothing goes to or touches the subject. Over the last ten years, great strides have been made in increasing the resolution and sensitivity of medical videothermography systems while decreasing their size and operational complexity. For example, the Inframetrics 600M color thermograph can differentiate between temperatures as little as 0.15 degrees C apart and can visualize areas ranging from one square centimeter to the entire body at once. The unit can quantify differences in heat and record on Polaroid and 35 mm film as well as videotape. A special computer interface/software package permits quantified comparison of many images simultaneously. The device fits on a 2 X 3 foot cart when it is in its "ready to use" configuration. An absolute temperature reference always appears on the screen so the actual temperature of an object being viewed is always known and day to day

comparisons can be made. Contact thermographs consist of a plastic screen about 18 inches on a side which is pressed against the part of the body to be visualized. The screen contains closely spaced pixels of chemicals which change color at different temperatures. Thus, a color image representing body heat is produced from the color at each pixel. These devices are very limited in temperature range and can not be used for long term recordings because the pressure of the plastic screen against the body changes the surface heat patterns.

Medical thermography is still in its infancy but has become accepted medical practice in several areas. Its most common medical use has been in finding objective evidence for reported pain not detectable by other means. For example, positive thermograms are acceptable in court as sufficient to establish the presence of low back disorders causing low back pain (Raskin et al. 1976, Wexler 1981, and Breckler 1980). Thermography has been used for differential diagnosis of reflex sympathetic dystrophy (Uematsu et al. 1981), rheumatic diseases (Ring 1975), insensitive feet and stumps (Bergtholdt and Brand 1975), diabetic myopathies (Cronin 1975), chronic pain of unknown origin (Hendler, Uematsu, and Long 1982); and as a screen for appropriate amputation level, breast cancer, and cardiovascular disease (Winsor and Winsor 1975), and referred pain (Hobbins 1982). Although no excellent, blinded, comparative technique studies have been performed, thermography has recently been accepted by the AMA as a valid method for assisting in the diagnosis of many conditions and as a primary method for confirming presence of reflex sympathetic dystrophy. Papers such as those by Goodman et al (1985) and Devereaux et al (1984) indicate that thermography is consistently of value in diagnosing stress fractures when compared with results of bone scans (the gold standard for demonstrating the presence of stress fractures). The technique is rapidly gaining wide acceptance for this use.

We have been using videothermography for over six years in a clinical research setting and have found that it is consistently reliable for detecting lower extremity pain problems (Sherman et al 1987). We are currently using thermography to elucidate mechanisms through which phantom limb and body pain are manifested (Sherman 1984, Sherman et al 1986, Sherman et al 1987) and as part of an evaluation of new methods for diagnosis of low back pain (Funded VA merit Review) and lower limb pain. We feel that thermography can grow to be a powerful tool in aiding the early detection and evaluation of status for many disorders which have changes in near surface blood flow among their manifestations.

Typical thermographic studies of chronic pain patients usually either follow one or two subjects through a series of evaluations (Sherman 1984) or show the results of one evaluation for a small group of patients with similar diagnoses (Sherman et al 1986). Unfortunately, virtually all articles on the use of thermography for evaluation of chronic pain are very similar in spite of the number of years the technique has been in use and the extensive claims made for its efficacy in detection and demonstration of various pain syndromes discussed above. Other than our own work (e.g. Sherman et al 1987), We have not been able to locate any blind, controlled studies in which such variables as intrasubject change with both time and pain intensity were taken into account. Uematsu is the leading investigator and reviewer in this field (1976) and has published papers (Uematsu 1985, Uematsu et al 1988) in which the stability of temperature differences in paired extremities are compared. Green et al (1986) found a five percent false positive rate when three blinded thermographers evaluated thermograms of 100 normal subjects. Feldman and Nickoloff (1984) have published the

first major set of thermographic standards for normal peoples' upper backs and arms we are aware of. Although subjects were thermographed only once, the study was large enough to permit definition of the expected range of normal but not expected intrasubject variability. Their paper discusses asymmetries and lists other thermographic studies using normal controls. Harway (1986) has discussed some of the methodological issues involved in making good thermographic recordings of the extremities. His paper summarizes the work in this area to date.

Parr et al. (1985) followed Raynaud's syndrome subjects over time. Drummond and Lance (1984) took sequential pictures of cluster headache patients through the course of a headache and have data on the same patients both when in pain and when pain free. This method of gathering data contrasts with the study of the same disorder by Kudrow (1985) who used large numbers of subjects observed once to gather significant information. Both of these studies provide excellent data. However, they make use of a technique which has not really been demonstrated to be sufficiently free of methodological problems to insure that the data are replicable and reflective of underlying physiological parameters. In short, there does not seem to be more than tantalizing evidence that thermography is a valuable clinical technique for evaluation of pain. The proposed studies will fill virtually all of the gaps in determining whether thermography is a valuable tool for predicting onset of lower limb problems and detecting stress fractures.

(4) Use of shock absorbing inserts for control of lower limb pain: See the introduction to phase two below.

BODY:

a. Overview: The basic structure of the program was presented in the introduction and is illustrated in Figure One on the next page.

b. Subjects:

(1) Number, age, source, and sex: The subjects will be soldiers just entering basic training at Ft. Sill and soldiers who are non-trainee patients at FAMC. Our pilot studies with soldiers indicate that almost all experiencing pain in the lower extremities will show abnormal thermograms, so the number of subjects will be predicated on the need to establish a rate of false positives and negatives (sensitivity of the technique). We will not be able to predict exactly how many subjects will be required until power analysis techniques are applied to initial data. However, we do know from our pilot data that no less than 100 subjects actually reporting pain in each of the three study areas could be useful in establishing sensitivity. For study one, since a minimum of twenty percent of trainees experience pain in these areas which is not due to obvious trauma, and each initial training battery has about 180 trainees, we will have to screen a minimum of 9 training batteries before training begins to insure that sufficient trainees subsequently report to health clinics for treatment of pain in the lower extremities which occurred during training. Based on our and others' experience in soliciting participation in minimal risk studies, we anticipate that a minimum of 95% of the trainees will agree to participate in the study. The number of batteries screened may have to be

increased to ten if the number of trainees agreeing to participate falls substantially below this rate. This will not effect the total number of subjects participating in the study. This will require a minimum of one year with the likely requirement for continued data gathering and reduction for a second year if we use one thermograph. This fits well with the availability of our professional resources. For study two, Our pilot data indicates that although 100 subjects would be sufficient to establish the efficiency of the technique, the need to clearly differentiate between the results of three heat sensing techniques as well as between relatively physically stable soldiers at FAMC and relatively physically labile trainees at Ft. Sill will require an additional hundred subjects and fifty controls from each site. The subjects will be male and female soldiers between the ages of 18 and 40.

(2) Inclusion and exclusion criteria: For trainees at Ft. Sill, the only entrance criterion is willingness to participate in the study while the only exclusion criterion is being in overall good health. For soldiers at FAMC, the entrance criteria are (a) being within the age limits, (c) not being a trainee, and (c) being suspected of having a NEW stress fracture. The exclusion criteria are (a) having any significant medical problem other than the suspected stress fracture, (b) not being relatively physically stable, (c) having a skin problem which would preclude use of contact thermography, and (d) having a history of stress fractures.

(3) Subject identification: During participation, subjects will be identified by their names and social security numbers because experimental data have to be related to results of standard medical tests. However, all records relating experimental results to subjects' names and numbers will be kept locked in a file cabinet at each participating site. At the end of participation, a code number will replace the names and social security numbers on each record. The key relating the code to the subjects' names and social security numbers will be kept locked in the PIs' files. This is necessary in case valuable clinical data is produced by the study which should be shared with the subjects.

(4) Subject assessment: see the following evaluation section.

(5) Risk to benefit ratio: maximum benefit to minimum risk. There are no risks involved in having heat recordings made of the intact skin surface. All other tests are required by the physical condition and would be performed regardless of whether the subject was participating in a study. At Fort Sill, no unit training time will be wasted as all evaluations will be performed during the three day initial in-processing period or while waiting for appointments at the troop medical clinic. At FAMC, The subjects' only contact with research evaluations will be two ten minute, harmless recording sessions. All other tests and examinations are standard at both sites.

(6) Precautions, corrective actions, and special care: none.

b. Project medications: none.

FIGURE ONE — STRUCTURE OF PHASE ONE

USE OF BODY SURFACE HEAT PATTERNS FOR PREDICTING AND EVALUATING ACUTE LOWER EXTREMITY PAIN AMONG SOLDERS

STUDY ONE
Predictive efficiency of thermography for lower limb injuries

1,620 trainees in 9 training batteries asked to participate as they arrive during fill week.

baseline one - performed as trainees arrive and are waiting for final assignment to training.

baseline two - performed at the end of fill week.

soldiers who never report to sick call: normative data base

soldiers reporting to sick call for any reason

200 trainees not attending sick call for lower limb pain or trauma act as controls for lower limb pain group controls in study one.

all trainees attending sick call due to non-traumatic lower limb pain

suspect stress fracture? yes / no

thermograms & lower limb exam at each visit by orthopedic surgeon, 50 of controls simultaneously act as controls for study two.

thermograms, lower limb exam by podiatrist & videothermograms, pain diagram, biomechanical evaluation, and all required tests at each visit.

STUDY TWO
Efficiency of thermography for diagnosis of stress fractures in the lower limbs

a. STRESS FRACTURE SUSPECTS: 200 patients suspected of having stress fractures (approximately 150 soldiers at FAMC in stable level of physical condition and 50 trainees at Ft. Sill to provide a comparison of stable vs. changing physical condition)

2 sessions approximately one week apart: contact thermography, videothermography, heat scan, and physical exams by an orthopedic surgeon and a podiatrist.
+
one X-ray & bone scan

b. 100 CONTROLS:
(1) 50 normal volunteers from the same groups as the "physically stable" stress fracture group at FAMC
(2) 50 controls for the "physically labile" trainees drawn from the

Two sessions approximately one week apart:

contact thermograms, heat scan, lower limb physical exam as above. NO x-rays or bone scans.

c. Evaluations:

(1) Thermographic recordings for study one: Subjects will be recorded in large groups in a temperature regulated environment with drafts reduced to a minimum. Subjects will be barefoot and wearing short pants. Each will wait for the session while laying down with the bottom of the feet in the air for a minimum of 15 minutes to allow body temperature to stabilize. Smoking and use of caffeine and alcohol are normally prohibited for several hours before a thermogram because they effect near surface blood flow. Control of these factors during the baseline sessions is largely beyond our control. However, trainees are normally not permitted to smoke or drink alcoholic beverages and we will request that they not use caffeine for an hour before the baseline and medical clinic sessions. Trainees who are secretly smoking or drinking alcohol are not likely to stop at our request. We do not feel that lack of control of these factors will invalidate the study because there would be the same lack of control when the technique is actually used to predict which trainees will are more likely to report lower limb dysfunctions. Privacy is not an issue as only the legs are exposed. At the end of the equilibration period, the bottom of the feet will be thermographed using an Inframetrics model 600M videothermograph. The instrument is capable of resolving temperature differences of 0.1 degrees Celsius and is sensitive to the heat created by blood flow patterns (spectral range of 8 - 12 micrometers) up to 1.5 cm. deep. Thus, all heat sources in a structure as thin as a foot would be visible but only a diffuse reflection of heat sources deep in the leg are directly visible. The device produces either grey tone or color images on a television screen. The video images are recorded on videotape and Polaroid photographs for later computer analysis at FAMC. Sensitivity is adjusted so that the computer can differentiate between 0.1 degree C levels. However, during the actual analysis, differences of less than 0.5 degrees will be discounted as they are within the range of normal variation (see the introduction). The model 600M thermograph has an internal temperature reference so day-to-day changes in temperature can be objectively related. After the bottom of the feet are thermographed, the subject will stand up and the tops of the feet and the front and side of the legs will be thermographed while the back of the legs are equilibrating. The backs of the legs will be thermographed after all standard tests are completed so the back of the legs can be equilibrating during the tests. Similar thermographic recordings will be made of all recruits reporting to sick call with non-traumatic lower extremity pain at each visit while they are waiting to be seen. As detailed in the introduction, a series of recruits reporting to sick call without lower extremity problems will be recorded in the same way.

(2) Body heat evaluations for study two: The videothermography will be performed exactly as stated for study one. Sessions will be in a temperature controlled environment and subjects will be prohibited from smoking and using caffeine for two hours prior to the test. Subjects will be prohibited from using alcohol for twelve hours prior to the test. After each view is taken, the beam thermometer will be run along the surface just photographed by the videothermograph and measurements will be taken along the distal-proximal midline of the surface at approximately 2.5 cm intervals. After the beam thermometer has been run across the surface, the contact thermograph will be pressed against the surface and a grey-tone videotape will be made of the image produced. This will permit computer comparison of the images produced by the contact and video thermographs.

(3) Other evaluations: All other evaluations for both studies are the standard, clinical, podiscopic, and biomechanical evaluations required for evaluation of pain in the lower extremities. The podiscopic evaluations will be filmed so the data can be directly compared to the thermographic data. Every subject in study two and during the "sick call" phase of participation in study one will be examined by according to criteria set by an orthopedic surgeon and a podiatrist and will fill in a diagram (Figure Two on the next page) of the lower extremities indicating location, description, and intensity of the pain. Every subject suspected of having a stress fracture will have both x-rays and a bone scan. These tests are now standard for this condition at both FAMC and Ft. Sill so are not part of the experimental evaluation.

(4) Schedule of evaluations and interrelationships between the two studies: See the figure for details of subject assignment and scheduling. The key interrelationship between the studies is that when trainees at Ft. Sill who are participating in study one (predictive value of thermography) and are suspected of having stress fractures, will also participate in study two (thermographic evaluation of stress fractures). Fifty of the trainee control subjects from study one will also serve as

controls for the trainees in the stress fracture study. All of the Ft. Sill trainees in the stress fracture study will be recorded at Ft. Sill so a contact thermograph and a heat beam meter will be located at Ft. Sill as well as at FAMC.

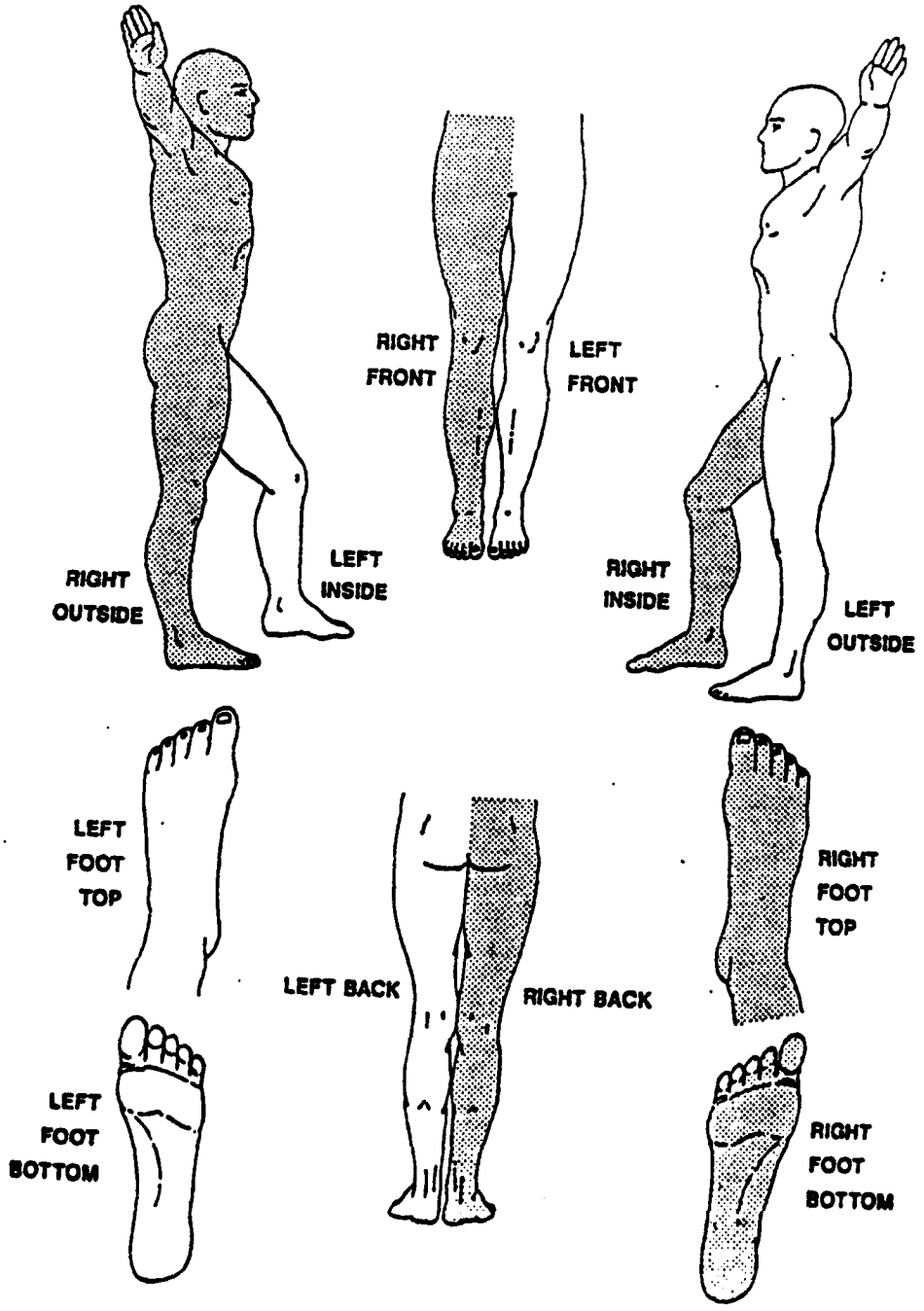
d. Data Evaluation:

(1) Thermographic data: All data will be reduced and analyzed using the thermal computer interface and program as well as the statistical programs and resources at FAMC. Intrasubject thermograms of the lower limbs including the feet are compared with adjacent and non-painful contralateral areas to determine differences in pattern of temperature and in the actual temperature at several points. Intersession differences are calculated from actual temperature differences between painful and pain free areas using a special computer program at FAMC. Half a degree is the amount of normal variability, so none of the data is considered to include reliable differences unless differences in temperature greater than half a degree are consistently present. Intersubject comparisons are made the same way. Each thermogram is rated by the computer as normal or abnormal depending on whether significant (greater than 0.5 degrees) asymmetries are found. The heat beam readings are evaluated the same way. Thus, a heat beam recording is considered abnormal if corresponding readings from the painful and non-painful sides are more than half a degree different.

(2) Statistical associations: For study one, the two baseline thermograms performed on each trainee will be compared with each other to establish the normal level of variability for the individual. All of the baseline thermograms will be evaluated to establish the rate of "positive" findings and normal variability in an asymptomatic group. When trainees come to sick call for non-traumatic leg pain, their thermograms will be compared with their baseline thermograms and subsequent thermograms taken at subsequent visits to sick call to evaluate individual changes from

FIGURE TWO LOWER EXTREMITY DIAGRAM

Trainees reporting lower extremity pain indicate the location, intensity, and description of their lower extremity pain on the diagram each time they report for sick call.



baseline and changes as the problem resolves. The thermograms will be divided into groups depending on the final diagnosis for each trainee and an attempt will be made to identify characteristics for each diagnosis. If the attempt appears successful based on computer identification of patterns, a group of five raters who are not aware of the diagnoses or of which set of thermograms relates to which diagnosis will attempt to sort individual thermograms into categories. See Sherman et al, 1987 for a detailed explanation of this technique and the associated statistical analysis.

Thermograms of trainees reporting to sick call for non-pain and trauma related problems (e.g. colds) will be related to their baselines to establish the expected differences due to training. Their thermograms will be related to those of the above trainees reporting lower leg pain to ascertain group differences. If there are no differences between the baseline thermograms of the trainees being seen for colds and etc. and those not reporting to sick call at all, the baseline thermograms of all trainees not having lower extremity pain will be considered equivalent in the analysis. The rate of false positives for the asymptomatic population will be calculated from the thermograms taken of these clinic controls. The rate of false positives and negatives for the symptomatic trainees will be calculated based on relationships with standard tests and reports of pain.

The efficiency of a test is frequently defined as the percentage of patients correctly classified as diseased or healthy (number of true positives plus true negatives divided by the number of tests times 100). We use efficiency as a measure of test effectiveness because it combines sensitivity and specificity in one measure. It is extremely sensitive to both false positives and false negatives which are of great interest to any evaluation of thermography. When relationships between report of pain and heat are evaluated, nonparametric Spearman's rank order correlation are used. A rank order test is required because pain ratings are entirely subjective and there is no way to be sure that the difference in pain between a zero and one rating is the same amount of difference between a four and a five. Nor is there any reason to think that any two people would either rate their pain the same or that the amount of change for one person would be rated exactly the same way an identical change would be rated by someone else. In other words, a "two" for one person could be a "five" for someone else. If both experienced the same degree of change in pain intensity, one might rate the change as from two to three while the other might rate the change as being from five to eight. For the same reasons, there would be virtually no validity to comparing pain - temperature change correlations between people. As this study is attempting to establish the predictive value of thermography, the most important tests are the non-parametric correlations between heat patterns, type and intensity of disorder reported, pain intensity and duration, and time lost from training. Of far less importance are the co-variate analyses and correlations which will factor out physical problems, height - weight - body fat ratios, location, description, and intensity of pain, and foot characteristics recorded during the examinations. Knowing how these factors effect the data may help explain variability in the key correlations and thus make the results more powerful but will not make them more meaningful. This is because there would be little value to screening baseline thermograms if a full battery of examinations of far greater than the usual detail have to performed also for the thermograms to be interpreted. In other words, the thermograms will have to stand as alone as possible for them to be valuable predictive tools.

The baseline thermograms of trainees having traumatic injuries to the lower extremities will be related to the other physical examinations done during the baseline period and to the thermograms of trainees who did not report lower extremity pain or trauma to determine whether the thermograms were different in any way.

For study two, the rate of false positives and negatives for each heat sensing technique will be calculated as described above by comparing the results of the particular heat test for a group of subjects with the results of the individuals' bone scans (our "gold standard"). This calculation will give the efficiency of each thermographic technique. The efficiencies of the three techniques and the rates of true positive findings will be compared using an analysis of variance. X-ray results will be compared with bone scans the same way. The true positive heat thermograms will be analyzed in detail to identify key sites where the heat beam sensor might be applied to produce replicable, positive identifications.

All data will be kept on computer disk and/or in hard copy for 15 years after completion of the study. The key relating the data to specific individuals will be kept locked in the PIs' files until it is destroyed at the completion of the study.

RESULTS OF PHASE ONE:

a. Duration of phase one: Funding became available in November, 1989 and, after numerous delays already detailed in prior reports, staff were finally hired by June so phase one of the project was actually completed in eighteen months rather than the two years initially anticipated. The technician originally hired at Ft. Sill had to leave the job unexpectedly due to her husband's unanticipated transfer as part of the Gulf war. It took CPO two months to replace her so the study was additionally delayed and less funds were spent then originally requested. Phase Two began on time this December and material is on order so the second phase should proceed on schedule.

b. Progress since the third quarter report for the second year of the study: An additional 201 trainees at Ft. Sill participated along with 27 new patients and 14 continuing patients at FAMC. The results of their participation are listed in Table One and follow the pattern set by prior groups. The notable exceptions are the seven trainees seen at FAMC who had completed basic training over one year ago and were currently participating in advanced individual medical training which included vigorous physical training. These pain free people were included to begin ascertaining whether there was a problem with false positives and whether asymmetrical temperatures persisted after basic training. Of the seven run to date, only one was within the normal limits of symmetry shown by other studies. Four showed asymmetries of between one and 1.9 degrees, One had an asymmetry of between 2 and 2.9 degrees and one between 5 and 6 degrees. This is contrasted with five similar subjects who were not in physical training programs who all produced symmetrical readings.

TABLE ONE

SUBJECTS PARTICIPATING IN PHASE ONE OF THE LOWER LIMB PAIN STUDY

DURING THE SECOND YEAR'S FOURTH QUARTER

A. Summary of Lower Limb Pain Study at Ft. Sill - phase I only

Data include information from March '91 to December '91
Total number of subjects 201

Total number of subjects not seen for leg pain during basic training = 129

Total number normal baselines = 63

Total number abnormal baselines = 92
Abnormal baselines with asymmetries between 1 and 2 degrees 66
Abnormal baselines with asymmetries greater than 2 degrees 26

Total number of subjects seen for leg pain during basic 46
Total number of baselines with asymmetries 33
Total number normal baselines 8
No baseline 5

TABLE ONE IS CONTINUED

TABLE ONE - CONTINUED

SUMMARY OF SUBJECTS SEEN WITH LEG PAIN
****

Main Problem	Total	Baseline results	Therms during Basic results
STRESS RXN	18	16 ASYM.	14 ASYM.
			2 WNL
		2 NO BASELINE	2 ASYM.
STRESS FX	7	6 ASYM.	6 ASYM.
		1 NO BASELINE	1 ASYM.
DISPLACED FX	1	1 WNL	1 WNL
SPRAINS	3	1 ASYM.	1 ASYM.
		1 WNL	1 ASYM.
		1 NO BASELINE	1 ASYM.
PES PLANUS	1	1 WNL	1 WNL
PES CAVUS	1	1 WNL	1 ASYM.
TENDINITIS	3	2 WNL	1 ASYM.
			1 WNL
		1 NO BASELINE	1 ASYM.
GENERAL FOOT PAIN	7	5 ASYM.	2 ASYM.
			2 WNL
			1 NO THERM
		1 WNL	1 ASYM.
		1 NO BASELINE	1 ASYM.
GENERAL LEG PAIN	2	2 ASYM.	2 ASYM.
PFJS	3	1 ASYM.	1 ASYM.
		2 WNL	1 ASYM.
			1 WNL
NUMBNESS IN FOOT	1	1 ASYM.	1 ASYM.
NO RX SOUGHT FOR LEG PAIN	129	92 ASYM.	
		63 WNL	

TABLE ONE CONTINUED

TABLE ONE CONTINUED

B. Lower Limb Pain Subjects seen at FAMC

Data include new patients from June 91 to present.
Total new patients 27
Total therms 58
Total continuing patients 14 with a total of 22 thermogram visits
Total all thermograms from June 91 to Dec 91 72

Problem	Number of pts	Number of visits	Results of Therms
R/O RSD	4	13	Asym.
Stress Rxn	2	4	Asym.
Stress Fx	4	12	Asym.
Tear Inter. membrane	1	1	Asym.
Chronic knee pain	1	2	Asym.
Chronic foot pain	2	5	Asym.
s/p Crush injury	1	2	Asym.
Leg & back pain	1	1	Asym.
Shrapnel wounds	1	2	Asym.
Metatarsal Fx	1	2	Asym.
s/p TKA	1	2	Asym.
No Pain Control (no PT)	5	5	WNL
No Pain Trainees in PT	7	7	6 Asym.

c. Results of phase one's project one (lower limb pain at Ft. Sill):

(1) Subjects: Data from 557 recruits has been recorded.

(2) Baseline: of the 548 baseline recordings, only 209 were within normal limits.

(3) Clinic Visits: Twenty-six "control" subjects who visited the clinic due to problems not related to the lower limbs or to circulation (e.g. colds) were videothermographed. Of the seventeen who produced abnormal thermograms during the baseline, all but one produced abnormal ones at the clinic. Of the seven producing normal ones, five had been abnormal during the baseline period. The problems evaluated and the thermographic results are detailed in Table One.

d. Results of phase one's project two (lower limb pain subjects at FAMC):

(1) Subjects: 73 subjects were recorded at total of 167 times. Eleven had knee pain, nine had pain throughout most of one leg in combination with back pain, four had stress fractures, three had RSD, four had peripheral nerve damage (sciatic, peroneal, sural, mixed with lower limb weakness), two ankle pain, two plantar warts, and two generalized leg pain with no know etiology. The others were pain free controls.

(2) Comparative test routine and rationale:
Three forms of thermography were compared: video thermography, contact thermography, and surface temperatures taken by an infrared thermometer. Video thermography is the state of the art in thermography and provides detailed and accurate picture of the heat that reflects off a body. This was considered the standard by which the other two forms of thermography were measured.
The subjects were first video thermographed, then had surface temperatures taken, and lastly had contact thermograms taken. The procedures were done in this order to eliminated any false patterns that might have been produced by the contact thermograph since it involves holding an inflated pillow against the skin for up to 30 seconds. Video thermography involves no physical contact to the patient. This prevents the apparatus itself from influencing the results and eliminates the need to take additional infectious disease precautions. The field of vision of the video thermograph camera allows a small area to be viewed, such as a patient's toes only, or an area the size of an entire leg can be viewed. This allows one to scan a large area readily or to observe a small area for detailed thermographic patterns. The videothermograms taken are continuously videotaped so that the data observed is always recorded. The video thermograph machine provides a color gradient at the base of the video screen that show what color corresponds to what temperature. The color gradient can be adjusted so that each variation in color represents a temperature difference of 0.25 degrees C. The machine is accurate to 0.1 degrees C and can give a temperature of a specific area being thermographed. The infrared thermometer was used with a modified tip so that the thermometer would constantly be held a uniform distance of about 1 Cm. over the skin's surface. Temperatures were taken of a point on one side of the body, and then immediately the temperature was taken at the corresponding area of the body. The temperatures were then recorded on a

body diagram. The temperature differences observed with this method are very similar to the temperature differences observed with the video thermograph, but the following may account for why some temperature differences may vary. The video thermograph camera is like a video camera and projects everything in a two dimensional plain. For areas such as the top of the feet that were not thermographed flat to the camera due to their shape, the temperatures observed with the video thermograph may be different than those taken with an infrared thermometer. This is because the infrared thermometer is always held the same distance from the skin with no angle. The video thermograph shows a very detailed picture of exactly where temperatures are observed. This makes it very easy for the thermographer to concentrate on the specific areas that are effected. The exact point at which the temperature difference is the greatest can easily be detected and recorded. With the infrared thermometer, temperatures were taken at set areas and may not have always reflected the point where the greatest temperature could be observed. This may have diminished the temperature differences observed with the surface temperatures.

There were standard areas where the surface temperatures were always taken. The areas chosen allowed us to map out a relatively detailed picture of heat patterns of the leg and foot area. With more attention to the task of developing a set method for taking surface temperatures of lower limbs, this form of thermography could be exceptionally useful, in the assessment of lower limb pain. The contact thermograph system is a series of flexible pillow detectors containing crystals that change color to correspond to a specific temperature. The pillow has a transparent window, allowing the thermographic image to be observed and photographed. The contact thermograph system has eight detector pillows so that thermographic images of a wide range of temperatures can be recorded.
Similar to the video thermograph, the contact thermograph has a color scale on each window that states what temperature each color corresponds to. This is determined by calibration at the manufacturer. Temperature differences that are required to produce the various colors do not occur in standard set increments, but the differences between each color can vary from 0.3 degrees C to 1.1 degrees C. The manufacturer claims this method is accurate to within 0.2 degrees C. Since beginning the study we have had to have the system recalibrated once. This is because the crystals will "drift" and the temperature required to produce a specific color can change over time. The procedure of taking a thermograph with this method involves holding the detector against the patient's skin for about 20 seconds. Then the detector is pulled away from the patient to flatten the pillows surface so that the image can be photographed. The thermographic image changes as the detector is taken off the patient's body. If there is a camera malfunction or a time delay the picture will change or be completely lost. Since the pillow detector had to be in a flat position to be photographed without glare, the image appears in a slightly distorted shape, thus the thermographic information may also be distorted. There were patients that were seen with a condition that was too painful for the patient to withstand even the light pressure of the detector against the skin preventing us from being able to use the contact thermograph. Also, if a patient had an open skin wound, rash, or a fresh surgery scar this procedure was not performed. At the early stages of the study we tried to get a contact thermograph of the entire leg and foot area. The size of the individual pillow detectors is about 12 inches by 9 inches. Due to the shape of the leg and foot areas, only a fraction of the area can be

thermographed at a given moment. We found that the edges of the detectors would cool the skin and produce a cold line across the skin in the areas that it touched. This prevented us from being able to thermograph the entire leg area. This method alone can not give a thorough thermographic image of the lower limb area.
A specific pillow is chosen so that ideally the majority of the thermographic image should appear in the center of the pillow's temperature range. This was often difficult if not impossible. Often a patient's body would be to cold to be observed in the range of even the pillow with the lowest temperature detecting ability. The leg and foot areas often have temperature differences that are greater than a few degrees. With some patient's, the left and the right side could not be observed with the same pillow. This tells us that there is a temperature difference but does not allow us to determine what that difference is. Although the pillows are calibrated to match up a specific color to its assigned temperature, often the same body area would produce a different temperature reading with the use of a different pillow. This may not be that critical of a factor since relative differences from right to left are what we are trying to determine. However, since the study to date has shown that temperature differences may occur in the lower limbs that are too great to fit in the range of a single detector, this method is not an effective or accurate diagnostic measurement. The detector pillows needed to be inflated in order to produce the thermographic image. The pillows are not air tight and lose air quickly and constantly need to be re-inflated. The system comes with warnings not to over inflate the detector pillows, as this would permanently damage their capabilities. The system does not have any pressure gauges or other measurements to determine what the optimal air pressure should be inside the detector pillows.
Certain areas of the lower limbs could fit within the field measured by the detectors such as the bottom of the feet. If both the right and left feet are relatively symmetrical in temperature, and there was not much variability in the temperature of the foot from heel to toe, then a relatively clear picture could be obtained. The thermographic trends observed when an adequate thermographic image was obtained followed the trends seen with the other forms of thermography. Contact thermography may be most useful at measuring thermographic patterns qualitatively on a small flat surface of the body.

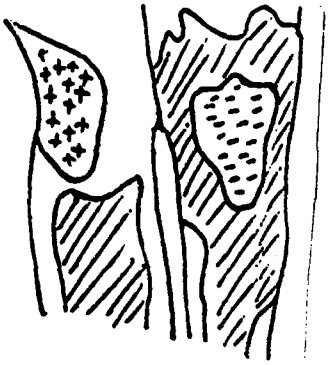
(3) Results of comparisons of the three techniques:
The videothermograph was consistently simple to use and could visualize all required areas. For those regions upon which the pillow could be pressed, the contact thermograph always showed a difference when the videothermograph showed one. However, the actual amount of difference was usually not calculable to the problems discussed above. Thus, the device could be used to pick up problems but not to track their progress across sessions. The infrared thermometer always showed the same temperatures as the videothermograph and could measure the temperature virtually instantly anywhere on the limbs with equal ease. It has none of the problems which make the contact thermograph cumbersome and ineffective. However, it only reads one temperature at a time rather than producing a multitemperature picture of the limb. In order to use the temperatures generated by the thermometer, many measurements must be made on each limb. The measurements must be made of exactly paired areas of the limbs or the measurements are useless. An illustration of temperature differences is produced by noting differences onto a picture of a limb which is overlaid by a grid. This takes longer than taking a videothermogram but about the same amount of time as it takes to use the contact thermograph. This is because the contact thermograph's pillows have to be changed and adjusted frequently. The following figures illustrate typical problems which arise when attempting to utilize the contact thermograph and provide a comparison of its output to that of the videothermograph.

FIGURE THREE

INTERPILLOW CALIBRATION PROBLEMS WHICH PREVENT USE OF CONTACT THERMOGRAMS FOR DETERMINING ABSOLUTE DIFFERENCES BETWEEN LIMBS WHICH ARE OF TOO DIFFERENT TEMPERATURES TO BE VISUALIZED ON THE SAME PILLOW

The color Polaroid pictures produced by the thermographs have been traced so that their patterns will show on xeroxed copies of this report. Different temperatures are shown by different patterns of crosshatching. Significant asymmetries are shown when paired areas of the limbs have different patterns.

Videothermogram showing both limbs. The areas shown by pluses and minuses are 5.4 degrees different. Differences of this magnitude are common and changes must be tracked in order to determine progress toward resolution of the problem.



Contact thermograms taken of the same limbs moments later. Two pillows had to be used to get both limbs into range of the pillows. The important point here is that the limb shown at the left of each drawing is in range for both pillows. It shows as 29.1 degrees in the left picture (the Xs) and as 29.7 degrees in the right picture (the dots). This common problem means that we can not determine the actual difference between two limbs when the two have to be visualized on different pillows.

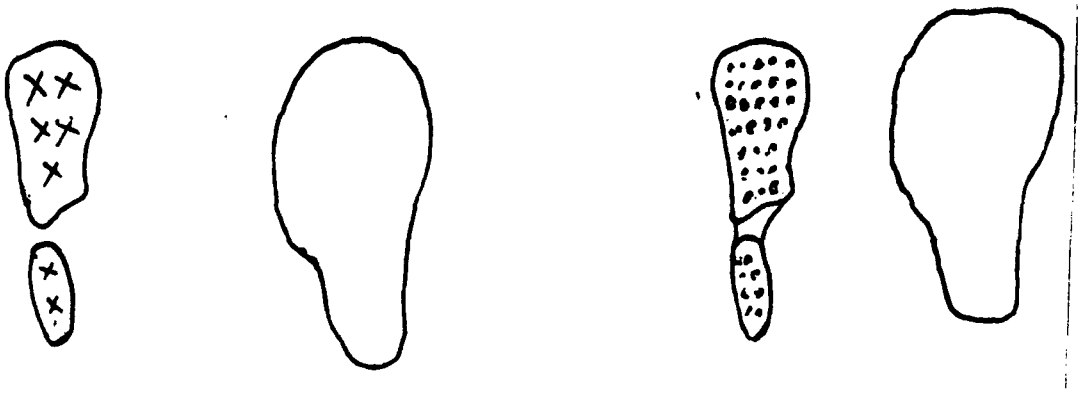


FIGURE FOUR

EFFECT OF THE CONTACT THERMOGRAPH FRAME
ON ABILITY TO PROPERLY VISUALIZE AREAS

The redrawn videothermogram on the left shows a crucial area in crosshatching which happened to be about the same size as the dark marks left on the skin by the frame of the contact thermograph shown on the right. These frame marks prevent proper visualization of an entire limb without waiting for the marks to fade over a period of about ten minutes. This makes the evaluation take so long that it is impractical.

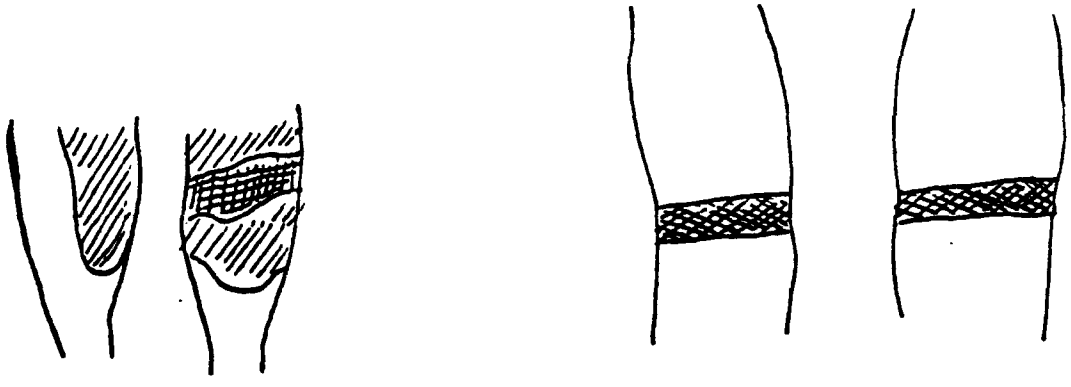
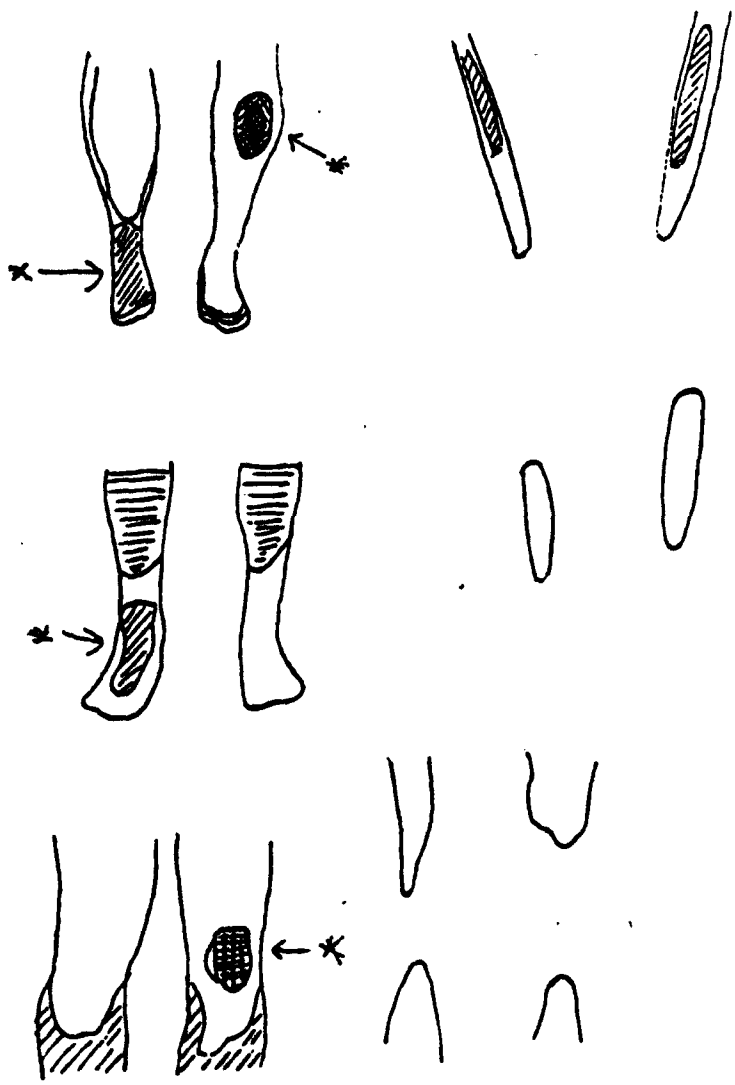


FIGURE FIVE

EFFECT OF THE CONTACT THERMOGRAPH'S INABILITY TO VISUALIZE HIGHLY CURVED SURFACES ON ITS ABILITY TO DETECT CRITICAL ASYMMETRIES

The redrawn videothermograms on the left show the critical areas of asymmetry where marks on one limb are different from those on the pair in the same area. Note that the contact thermograph failed to make images of the critical areas because the curve was too great for the pillow to wrap around or get into. The top two images are of the front of the legs with the front of the ankles and sides of the legs missing in the contact thermograms. The bottom drawing is of the back of the legs with the backs of the knees missing in the contact thermographic views.



(4) Development of a grid pattern which permits utilization of a heat beam thermometer to accurately show patterns of heat asymmetries:

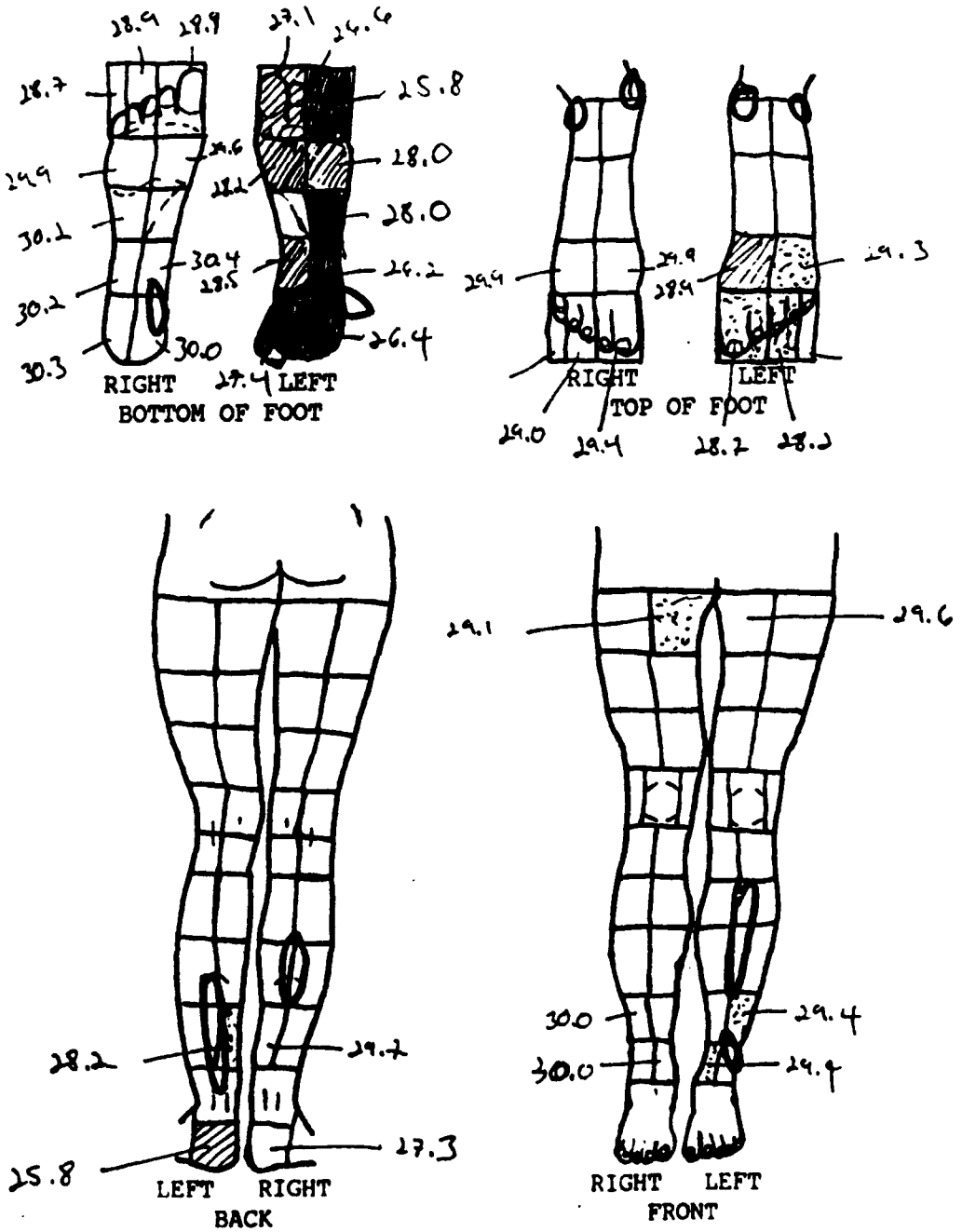
A grid diagram of the body was developed on which the temperatures taken by the digital infrared thermometer could be charted to make a temperature diagram of the body similar to that produced by the videothermograph. We tried numerous grid patterns with sections of various sizes to find an optimal pattern which would allow one temperature to be taken per grid section without losing any of the significant asymmetries shown on videothermograms. The grid pattern shown in Figure Six has been our best attempt to date. It has been prospectively tested with 122 lower limb pain patients (62 of whom were patterned twice) and only missed one small asymmetry on one patient. Other asymmetries on the patient were picked up so the interpretation of the overall body pattern was not changed. This grid has the advantages of permitting an overlay of the location of the patient's pain diagram as well as showing the amount of asymmetry. We intend to continue testing this grid pattern both at FAMC and Ft. Sill until we can establish confidence limits for its use on the types of subjects with lower limb pain normally seen at these locations.

FIGURE SIX

GRID OVERLAY FOR DEPICTING PAIN AND TEMPERATURE PATTERNS

1. Circle painful areas on grid diagram using a THICK LINE.
2. Take skin temperatures from side to side to fill in corresponding boxes.
3. Write in temperatures for each grid section.
4. When one grid box is at least 0.5 degrees cooler than the corresponding box on the paired limb, mark the cooler box as follows:

0.5 - 0.99 = ▭ 1.0 - 1.99 = ▨ >1.99 = ■



CONCLUSIONS:

a. Study One (trainees at Ft. Sill):

(1) Prevention of stress fractures: The most important conclusion of this study is that almost, but not quite, all stress fractures (not stress reactions) can be prevented among basic trainees if their activity level is reduced when they report pain in the shins which is sufficiently intense to prevent comfortable ambulation for about five days. This inadvertent finding was produced because trainees who complained of pain in this area received videothermograms after hurting for about five days. When the thermograms were positive, their activity level was reduced and they did not get stress fractures. This is probably the reason that the rate of stress fracture occurrence dropped from and average of eight per month prior to onset of the study to about one per month during it. We do not know what the rate of stress reactions was prior to the start of the study but there is no reason to feel that it changed as training patterns prior to report of shin pain did not change. At least 23 trainees had confirmed stress reactions during the study period. It must be emphasized that neither videothermograms nor any other sophisticated diagnostic technique are needed to maintain this reduction. The report of sustained pain the area should be enough. We recommend that this method for avoiding onset of stress fractures be tried on an experimental basis. We will do so as part of Phase Two if the command at Ft. Sill agrees.

(2) Asymmetrical pre-basic training baselines: Of 299 trainees who produced asymmetrical baselines in which the limbs were different by at least one degree Celsius (*the minimum required for a* "clinically" valid difference) , 116 (39%) experienced lower limb pain severe enough to require clinical assessment. Of the 209 who produced normal baselines, 59 experienced lower limb pain (28%). While this is a statistically significant difference ($X^2 = 9.96, p = 0.0016$), it is useless for deciding whether a new recruit should receive special pre-basic training toughening or even not be accepted at all. Of much more importance is the fact that 8 percent of those having lower limb pain sufficient to require treatment had asymmetries greater than 4 degrees while only 2 percent of those not developing lower limb pain ($X^2 = 7.65, p = 0.006$). Five percent with pain had differences greater than 5 degrees as opposed to only 1 percent of those not developing pain ($X^2 = 6.46, p = 0.01$). We are recommending that a trial screening program for all trainees at Ft. Sill be put in place using the inexpensive "first-temp" style infrared thermometer to detect people with asymmetries of five degrees or more so they can be given special attention. This should result in a significant decrease in the rate of occurrence of lower limb pain among basic trainees. We will perform much of this screening as part of phase two. The results of phase two of this study will determine the effects of reducing the intensity of repeated impacts on occurrence of lower limb pain so recommendations about trainees with baseline asymmetries of less than 5 degrees will be withheld until the results of this study are completed.

(3) The problem of false positives: As detailed in the results section above, seventy percent of the trainees produced abnormal baselines in that paired areas were asymmetrical by at least one degree Celsius. This accepted norm is based on a variety of studies reported in the literature including one done by LTC Sherman at Eisenhower AMC. These studies were all done with people of a variety of ages who were not in structured

training programs. Our initial studies with pain free controls at FAMC and Ft. Sill show that people in Army physical training programs are more likely to produce asymmetrical thermograms than similar people not in these programs. We have only run 22 pain free controls. Of these, all but five were in training programs. However, these five were all among the nine who produced symmetrical thermograms (differences between paired areas of the limbs less than one degree Celsius). Thus, there is a very real possibility that (a) we do not know what normal symmetry is for this age range and/or (b) people coming into basic training have already begun training at home prior to coming into basic training and have injured themselves as part of their home training. It is impossible to fully interpret the results of phase one until this question is answered. We would like to attempt to answer the question through two quick studies which will NOT require additional support from MRDC.

(a) As detailed in the third quarter report, we have proposed to work with MEP command to take thermograms of people who sign up for active duty six months or so before they actually come on duty (and thus, hopefully, have not begun an active home training program) as well as people who are about to enter active duty. This study is detailed in the "future plans" section below. It is vital to note that, although the Denver MEP station evidenced interest in participating, MEP command has not agreed to our performing this study. We need assistance from MRDC's command to explain the importance of this study to MEP command.
Copies of the following documents form Appendix A: A copy of the original 20 March, 1991 letter requesting permission from the MEP command; their reply dated 18 April, 1991 requesting further information; our reply dated 26 April, 1991 which included copies of the original protocol and all supporting documents; and, finally, their reply dated 22 May, 1991 which said that the study was of great interest but should be done a military facilities rather than at the MEPs. To us that meant that they had misconstrued our initial request or confused it with the supporting information they requested so we made numerous telephones to the MEP command over the next few months attempting to align their perceptions with our request. It eventually transpired that COL Black, the person at MEP Command who was coordinating their review of our request was in the process of retiring. His replacement was to contact us but never has. Since we may be putting another command in an uncomfortable position, we do not feel comfortable perusing this further without specific support from MRDC. **We will wait until we hear from MRDC HQ regarding political support for this study prior to recontacting MEP command.**

(b) People who should be demographically similar to basic trainees can be found in the young adult classes of the vocational schools and community colleges. We propose to work with Pickens Technical School and with Aurora Community College to identify people similar to our trainees. Those agreeing to participate will be questioned about their athletic programs and histories of injuries and then receive a thermogram if they have either minimal or vigorous athletic training programs (people with intermediate levels of physical activity will not be included as they would confuse the data). As 70% of the trainees produced abnormal thermograms, only 139 similar civilians with minimal athletic participation and history and another 139 with vigorous training programs need participate for us to be able to differentiate between the two types of civilians and our trainees at the 99% confidence level. This will tell us whether our trainees are thermographicly normal for their peer group.

b. Study Two: As detailed in the first annual report, the contact thermograph was a very surprising disappointment. It is very poorly constructed and cumbersome or impossible to use as required. It can not visualize important areas which have greatly curved surfaces such as the front of the ankles and the back of the knees. Although it is initially enticing to see an apparent image of the extremity's heat produced on a screen, the limitations of that image make it useless for the Army's needs both in the field and in fixed facilities. Due to the very limited number of degrees each pillow is sensitive to, most of the image does not appear. Neither of our sets of contact thermogram pillows are properly calibrated so the readings from one pillow can not be related to the readings on the one above or bellow it along the temperature range. This means that no absolute difference between two limbs can be generated in the frequent case where the temperatures of the limbs are so different that each has to be visualized using a different pillow. The infrared thermometer costs only a few hundred dollars and will probably be available at each field site since it can take body temperatures virtually instantly without risking contamination of the instrument by touching the patient. We are able to produce a picture of temperature asymmetries using this device as quickly as can be done using the contact thermograph. The difference is that differences between the limbs must be noted on a picture of the subject's limb rather than just referring to a photograph of an image. However, the notations produce an accurate assessment of the asymmetries while the contact thermograms just give a vague notion of problems at best. We have developed a grid system which can be used by virtually untrained personnel to produce an accurate picture of both temperature and pain patterns in the lower limbs within five minutes. If it turns out that heat patterns are valuable for screening soldiers, we will recommend the use of heat beam thermometers in conjunction with this grid system to perform the task.

c. Plan for the third year of program:

(1) Phase two will be performed as stated in the third quarter report and as already funded by MRDC.

(a) Effect of preventive utilization of orthopedic boot inserts on success in artillery basic combat training, pain, and leg heat patterns: This is the intervention phase of the study. It uses the information gathered in the first phase to assist in testing a simple intervention to prevent onset of lower limb pain. As documented in literature reviewed above, and substantiated by the initial results of this study, a minimum of twenty percent of soldiers request treatment for debilitating pain in their (1) knees, (2) lower legs and, (3) feet during basic combat training. This significantly interferes with their ability to successfully complete the program. A variety of boot inserts are available which the investigators have found effective in reducing the incidence of injury and pain in these areas among fully trained soldiers treated at Army Podiatry clinics in Germany and FAMC.

Method: We are in the process of issuing inserts to every trainee in alternate training batteries as the batteries are filled. This simplifies keeping track of which trainees have the inserts and prevents the current practice of sharing the few that are available between several trainees. The orthopedic shock absorbing inserts are using do not require

individualized fitting. They come in shoe sizes so all that has to be done is to distribute the inserts to the trainees after they receive their boots and sneakers. The trainees then slip the inserts into their foot wear and leave them there for their entire training cycle. The trainees are told to wear the inserts at all times when on duty. Each trainee from a battery participating in the study is checked for use of the insert by drill sergeants as part of the normal uniform inspection procedure. At the end of BCT each trainee fills out a half page questionnaire concerning their use of the inserts. We are screening each participating trainee's lower limb heat patterns as we did in phase one both prior to start of training (and prior to use of the inserts) and when they come to the TMC for any reason. Heat patterns are measured using the digital infrared thermometer tested during the first phase of the study instead of the expensive, complex, cumbersome videothermograph. We are comparing the training batteries with and without inserts for: (a) PT scores, (b) number of trainees graduating on time, (c) number of visits to the clinic for lower limb pain, (d) severity of lower limb injuries, and (e) changes in lower limb heat patterns. Differences between the batteries on (a) initial scores on the introductory physical assessment battery, (b) amount of overweight, and (c) percent body fat will be factored out so they do not influence the results. Each battery has 110 - 200 soldiers in it whom we can track (there are always missing records and people who leave training for a variety of reasons). A twenty percent lower limb injury rate means that we can expect about 40 soldiers in each battery to have lower limb injuries. Most of these are apparently related to physical stress on the lower extremities related to the training. Our pilot work involving use of these inserts with soldiers having similar pain problems at Fitzsimons Army Medical Center indicates that a reasonable reduction in these kinds of injuries brought about by the use of inserts would be about 25%. Thus, if the inserts are effective, we would be comparing batteries having an average of 40 injuries with those having an average of 30. In order to have a 90 percent chance of detecting a significant difference between the batteries at 0.05 (power analysis using the "z" test for proportions), 12 batteries (a total minimum of 1,320 trainees) would have to participate. Since half of the trainees will have the inserts and each trainee will need one pair for their boots and one pair for their sneakers, 1,320 pairs of inserts will be required to perform the study. At this time we do not plan to compare different types of inserts. However, if the insert we are familiar with and plan to use in this study does produce significant reductions in injuries, we will propose a comparative study of several styles and compositions of inserts.

Hypothesis: That the use of shock absorbing boot and sneaker inserts will produce a significant reduction (of about 25%) in number of visits to the clinic for lower limb pain and severity of lower limb injuries along with a corresponding increase in PT scores and number of trainees graduating on time.

Significance: Any methodology which can even marginally reduce the high rate of temporary disability occurring during initial training would significantly increase the efficiency of the training effort. Our pilot work shows that about 25% of the trainees now delayed in completing their training might complete it on time and with less visits to the clinic. This translates to ten more soldiers in each training battery requiring less extra care and time.

6) Literature on the preventive use of inserts and on choice of inserts: We are aware of only two studies reporting the use of inner soles to prevent overuse injuries of the type we see at Ft. Sill. In one study (a), a type of inner sole was used that did not change vertical impact forces. No change in injuries was reported. The second study (b) used the same type of cushioning inserts we propose to use. The authors found a decreased incidence of lower limb problems among Army basic trainees. They compared injuries among 237 randomly selected new recruits with injuries among 1151 similar recruits who did not wear inserts. Twenty-one percent of the group wearing cushioned inserts experienced overuse injuries relative to twenty-seven percent of the control group. This difference was significant at the 0.05 level.

We use the insert chosen for this study clinically (see pilot results in below) because they seem to work better than the others we have tried informally and because they have the lowest peak and peak pressure scores but the highest energy return scores of all inserts reviewed (c). Thus, they should be the best choice for the type of stress trainee's feet and legs are exposed to.

(a) Gardner LI, Dziados JE, Jones BH: Prevention of lower extremity stress fractures: A controlled trial of a shock absorbent insole. American Journal of Applied Physiology 78 (12): 1563-1567, 1988.

(b) Schwellnu MP, Jordaan G, Noakes TD: Prevention of common overuse injuries by the use of shock absorbing innersoles: A prospective study. American Journal of Sports Medicine, In Press, 1991.

(c) Frederick EC: Impact testing of insoles. Exeter Research 105 Haigh Road, Brentwood, NH 03833, (603) 722-4125.

Clinical experience / pilot work related to this phase:

(a) FAMC: We currently provide inserts of the type proposed to soldiers seen in the Podiatry Clinic at FAMC who are experiencing several types of lower limb pain (caused by such problems as stress reactions, flat feet, etc.) while performing their normal training and duties. They are relatively seasoned soldiers and are not training as intensely as the trainees who will participate in the study. However, the sources and types of pain are similar. The problems are corrected among about 80% of the soldiers who use the inserts regularly. This is based on a sample of about 300 soldiers seen over the last three years with follow-ups on about 250 of the soldiers ranging from three to twenty-four months.

(b) Ft. Sill: We provide inserts of the type proposed to both trainees and relatively seasoned soldiers. Our experience with seasoned soldiers is similar to that found at FAMC. When trainees come to the TMC having lower limb pain due to such problems as stress reactions, flat feet, and PFJS, they are issued inserts. The problems are corrected among about 55% of the trainees who use the inserts regularly. This is based on a sample of about 400 trainees who have had inserts issued to them over the last two years. As the trainees can only get care from our clinic, we know that any trainees who were not helped enough so that no further medical care was required would have come to see us so their data would have been in our records.

(c) Desert Shield/Storm: When four Orthopedic Surgeons from FAMC went to Saudi Arabia in support of Desert Shield/Storm, they were sent 2,000 pairs of the type of cushioning inserts we propose to use (500 pair to each). Virtually all were issued to soldiers reporting lower extremity and foot pain. The surgeons reported that they would have issued more if they had been available. We can not compile exact statistics on their effectiveness. However, the vast majority of the patients did not return for further care and those that did report back gave very favorable reports. All four surgeons stated that the insoles helped relieve foot pain among their patients.

(b) Effectiveness of videothermography in detecting and tracking the progress of lower extremity pain disorders among solders:

Introduction and methods: The progress reports for the first phase of this project show that thermography consistently shows asymmetries related to pain sites reported by most, but not all soldiers being seen for lower limb pain at FAMC's Orthopedic Clinic. A major problem faced by Orthopedic physicians is objectively determining the progress of lower limb pain problems toward resolution because the patients' reports of discomfort are frequently the only markers available. If an objective way to determine progress toward resolution could be determined, it would be easier to estimate how long it would be before soldiers would be ready to return to duty and the actual determination of whether a soldier was or was not ready to return to duty would be simpler. Thus, we propose to perform videothermographic recordings of all soldiers with lower limb pain seen at FAMC's Orthopedic Clinic. Each patient will be recorded every time they are seen at the clinic so medical records can be compared with thermographic results. The exact recording methodology as well as our initial attempts at establishing these relationships and the statistical techniques employed were detailed in the original protocol and have been reported elsewhere (citations a - d below). The pain problems we will concentrate on are those which are common in the military combat training environment which we see enough of at FAMC to permit development of predictive statistics. These include but are not limited to Reflex Sympathetic Dystrophy, stress reactions, stress fractures, knee pain, and foot pain.

Hypothesis: That heat patterns in the lower limbs will change consistently and predictably as lower limb pain disorders resolve so that they will be useful for: (a) objectively tracking changes in the problems (which also permits objective determination of whether a treatment is effective), (b) predicting rate of improvement so estimates of when soldiers may be able to return to duty can be made, and (c) assisting in the determination of when a problem is sufficiently resolved so that a soldier can return to duty.

Significance: It is currently difficult to objectively track the progress of most lower limb pain disorders. Development of a method which permits accurate, objective tracking of progress toward resolution (or otherwise) would permit: (a) determination of whether a treatment is working, (b) estimation of the rate of progress (so estimates of how soon the soldier could return to duty could be made), and (c) more accurate evaluation of whether the problem has resolved sufficiently so that a

soldier can return to duty.

Relevance to USAMRDC mission: If a way can be found to (a) roughly predict how long it will be before soldiers can return to duty, (b) provide an objective measure of whether treatments are working, and (c) determine whether the soldier has progressed sufficiently to return to duty will significantly increase the ability to predict manpower availability, increase the efficacy of treatment programs (by decreasing the time ineffective treatments are attempted), and decreasing the number of times soldiers reinjure themselves by being returned to duty too early.

Supporting literature for project two:

(a) Sherman R, Barja R, Bruno G: Thermographic correlates of chronic pain: Archives of Physical Medicine and Rehabilitation, 68: 273-279, 1986.

(b) Sherman R, Karstetter K: Relationships between RSD related pain and patterns of near surface blood flow: Stability of (1) concurrent changes due to treatment and over time and (2) relative locations of pain and of blood flow asymmetries. Proceedings of the 1990 annual meeting of the American Pain Society, 1990. p. 24 (Abstract)

(c) Karstetter K, Sherman R: Use of Thermography for initial detection of early Reflex Sympathetic Dystrophy. Journal of the American Podiatric Medical Association, 1991. (Article)

(d) Sherman R, Karstetter K, Damiano M: Stability of temperature asymmetries in RSD over time, with treatment, and changes in pain. Submitted to Pain, 1990 (Article).

(2) The study utilizing young adult students at a vocational school and at a community college described above in the conclusions section will be finalized and performed if approved by FAMC and the schools.

(3) If HQ at MRDC successfully helps us interest MEP command in evaluating people joining the Army, we will perform the following study: People processing through the Denver MEP station who are either (a) delaying their entry onto duty for between four and six months or (b) are leaving for duty within the next few weeks will be asked to participate in a study in which they describe their recent intensity of exercise and history of illnesses and have a thermogram taken of their legs and feet. Initially, 150 of each group will participate in the study. Power analysis will be performed to determine how many more subjects, if any, will be required to differentiate between the groups and our trainees. If we identify subgroups among the people about to leave for duty in which one has recently begun vigorous training after a history of minimal regular exercise while the other has a long history of regular, vigorous exercise, a minimum of 100 are likely to be required in each subgroup in order to differentiate between them (which brings the total number of participants to 350).

d. Administrative recommendation: When MRDC funds projects at Army

MEDCENs, consideration should be given to beginning the funding cycle when staff and equipn ent are actually available. For example, this project was funded in December of 1989 but CPO at FAMC did not permit us to bring staff on until June of 1990. This means that we had only seven months to perform the first year's worth of work.

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APPENDIX A

CORRESPONDENCE BETWEEN FAMC AND MEP COMMAND ON THE PROPOSED STUDY

1. ORIGNINAL REQUEST TO MEP COMMAND

HSHG-CI (340d) 20 March, 1991

MEMORANDUM FOR Commander, HQ, US Military Entrance Processing Command; ATTN: MEPCM; 2500 Green Bay Road, N. Chicago, IL 60064-3094

SUBJECT: Request permission to use the MEP station in Denver to perform a portion of the study entitled:
USE OF BODY SURFACE HEAT PATTERNS FOR PREDICTING AND EVALUATING ACUTE LOWER EXTREMITY PAIN AMONG SOLDIERS

1. The above study has been approved and funded by both the US Army's Health Services Command and Medical Research and Development Command (MRDC log numbers 89130004, #HSC-MRP-011-89 and 89111006, HSC-MRP-007-89). Almost one third of basic trainees develop sufficient pain in their lower limbs to significantly interfere with their training and, frequently, to prevent their graduating on time. Fitzsimons AMC is coordinating a study attempting to determine why this breakdown rate is so high. The study uses videothermographic (infrared heat photography) techniques to visualize heat emanating from the skin of the feet and lower limbs of trainees entering basic training. Heat patterns on the surface of the extremity's skin are caused only by blood flowing near the surface. Thus, this non-invasive technology permits us to quickly determine blood flow patterns indicative of underlying disorders.

2. In initial studies at Ft. Sill performed over the last eight months, the investigators determined that slightly more than half of the recruits arriving at Ft. Sill had abnormal blood flow patterns in their lower extremities. This means that a very significant proportion of them are likely to experience debilitating lower extremity pain during basic training which will prevent their graduating on time, if at all. Similar young men not entering the military have less then a two percent abnormality rate. The recruits may be doing considerable, poorly designed, "home" training in preparation for entrance into training which, in fact, causes disabilities which are not apparent until the physical stresses inherent in basic training brings them out.

3. The investigators propose to take heat pictures of young men processing through the Denver MEP station who are either (a) in a delayed entrance stage between four and six months prior to entering active duty or (b) virtually ready to leave for active duty. The actual number of people needed will depend on variability between the subjects but the investigators do not feel that more than 50 of each will be required. The

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videothermograph does not send anything to the subjects so is entirely harmless. The device sits on a small cart and adjoining rolling stand. It could be set up anywhere people who are already barefoot and bear legged pass by. The actual pictures take an average of two minutes to take but each participant would need to sit with his feet raised for five minutes prior to being thermographed in order to allow the heat to dissipate from the bottom of the feet. At the rate people are processed through the Denver MEP station, the study would require between one and two weeks to gather sufficient appropriate subjects. Each would be asked to read the attached subject explanation so they understand what they are involved in. They do not need to sign it because their names or other identifiers will not be recorded and there is no known risk to participating in the study.

4. MAJ Shamborn and Dr. Williams of the Denver MEP station have indicated interest in the study. Thus, if you approve, the investigators can coordinate directly with them.

5. For further information, please feel free to contact the principal investigator, MAJ(P) Richard A. Sherman directly at Autovon 943 - 3032/8167 or Commercial (303) - 361 - 3032/8167.

FOR THE COMMANDER

1 enclosure as stated

SHANNON M. HARRISON
LTC, MC
Chief,
Dept. of Clinical Investigation

APPENDIX A - CONTINUED PAGE 3

2. FIRST REPLY FROM MEP COMMAND

MEPCM (HSHG-CI, 3 Apr 91) (340d) 1st End COL Black/amd/LSN 792-3820
SUBJECT: Request Permission to use the MEP Station in Denver to Perform a Portion of the Study Entitled: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

Commander, U.S. Military Entrance Processing Command, 2500 Green Bay Road, North Chicago, IL 60064-3094 18 APR 1991

FOR Commander, Fitzsimons Army Medical Center, ATTN: HSHG-CI, Aurora, CO 80045-5001

1. The Medical Directorate has reviewed your memorandum and requests further information concerning the research project. Please send us a copy of your research protocol including a summary of the project; the hypothesis to be proven and purpose of the research based on prior studies with a bibliography; planned statistical analysis; the proposed use and value of the information obtained by the thermographic techniques; names of the investigators with back grounds; projected costs; the U.S. Army Medical Research and Development Command Committee additions or corrections to the protocol (if any) and a copy of their statement of approval.

2. Upon receipt of the above, we will be pleased to further consider your request.

FOR THE COMMANDER:

Encl
nc

KENNETH E. BLACK
Colonel, MC
USMEPCOM Surgeon

3. FAMC'S REPLY TO MEP COMMAND'S FIRST REPLY

HSHG-CI (340d) 26 April, 1991

MEMORANDUM FOR USMEPCOM Surgeon, COL Kenneth E. Black; HQ, US Military Entrance Processing Command; ATTN: USMEPCOM; 2500 Green Bay Road, N. Chicago, IL 60064-3094

SUBJECT: Reply to memorandum dated 18 April, 1991 with subject: Request permission to use the MEP station in Denver to perform a portion of the study entitled: Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers

1. Thank you for your initial review of our request.

2. As per your memorandum dated 19 April, 1991 with the above subject, the information requested is enclosed as follows:

a. The original research protocol including a summary of the project, the hypotheses to be proven, purpose of the research, planned statistical analysis, proposed use and value of the information obtained, names and backgrounds of the investigations, projected costs, and a bibliography.

b. The addendum to the protocol specifying why the original protocol has to be modified to include evaluation of soldiers at a MEP station. This includes the value of information gained from the MEP station and how we will handle it.

c. Fitzsimons AMC's IRC approvals of both the original and modified protocols.

d. MRDC's approvals of the protocol for funding and human use.

3. We do not project any cost of this project to the USMEPCOM.

4. We do not have and do not require final approval from MRDC to perform the modification to the original study. Although MRDC was sent a copy of our letter to USMEPCOM for evaluation of human use issues, we are awaiting your comments prior to finalizing our memorandum to MRDC informing them of our intention to perform the study. Although the original study is funded and approved by MRDC, this addendum can be performed using equipment and personnel supplied solely by HSC. As the addendum has already been approved by HSC, we do not require either MRDC's approval or comments other than as a courtesy.

FOR THE COMMANDER

6 enclosures as stated

SHANNON M. HARRISON
LTC, MC
Chief,
Dept. of Clinical Investigation

4. MEP COMMAND'S FINAL REPLY

MEPCM (HSHG-CI/26 Apr 91) (3404) 1st End COL Black/dmd/DSN 792-3820
SUBJECT: Reply to Memorandum Dated 18 April, 1991 with Subject: Request Permission to Use the MEP Station in Denver to Perform a Portion of the Study Entitled: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

Commander, U.S. Military Entrance Processing Command, 2500 Green Bay Road, North Chicago, IL 60064-3094 22 MAY 1991

FOR Commander, Fitzsimons Army Medical Center, ATTN: HSHG-CI, Aurora, CO 80045-5001

1. Your research protocol, SAB, and addendum have been reviewed.

2. The postulation that pretraining exercises cause thermographic changes in the lower extremities of U.S. Army recruits should be studied at military facilities and not at the MEPS.

3. Your study with the thermogram to attempt to prove its value in diagnosing and predicting lower extremity injuries in service members in a quick and non-invasive manner in field settings is of great interest.

FOR THE COMMANDER:

Kenneth E. Black

Encls
nc

KENNETH E. BLACK
Colonel, MC
USMEPCOM Surgeon